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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/810,231

03/25/2004

Mary Jo. A. Toomey

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EXAMINER

CHAPMAN, GINGER T

ART UNIT

PAPER NUMBER

3761

MAIL DATE

DELIVERY MODE

12/11/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/810,231	TOOMEY ET AL.	
	Examiner	Art Unit	
	Ginger T. Chapman	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-7, 10, 11, 45 and 47-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-7, 10, 11, 45 and 47-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Terminal Disclaimer

1. The terminal disclaimer filed on September 15, 2008 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 7,118,559 B2 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Status of the claims

2. Claims 1-7, 9-12, 44-45 and 47-52 are pending in the application.

Claim Objections

3. Claim 10 is objected to because of the following informalities: line 2 recites, "to removable enclose". The examiner is considering this a typographical error of "removably enclose". Appropriate correction is required.

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-7, 10-11, 45, and 47-52 are rejected under 35 U.S.C. 102(e) as being anticipated by Manera (US 6,706,031 B2).

5. With respect to claims 1, 45, 48 and 50, Manera discloses a fluid collection apparatus comprising a housing 50 having a needleless first mating portion with a first connector 24; and a

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holder 60 having a first end 68 and a second end 72 configured to receive an evacuated tube 30, the first end 68 defining a second mating portion 66 with a second connector 62 adapted to establish fluid communication with the evacuated tube (figs. 14-16); wherein the first connector 24 couples and sealingly engages the second connector 60 to releasably mount the holder 60 to the housing 50 to establish fluid communication therebetween, one of the first and second connectors being a male connector 60 and the other of the first and second connectors 24 being a female connector; and a base 22 disposed within the housing 50 to support holder and housing in upstanding relationship with respect to a support surface.

6. With respect to claim 2, Manera discloses the base 22 has a top opening (c. 3, ll. 61-62) for receiving the housing 50.

7. With respect to claim 3, Manera discloses the base 22 is adapted for standing on a support surface (fig. 4).

8. With respect to claim 4, Manera discloses the base 22 is configured to enclose the holder 60 (fig. 8).

9. With respect to claim 5, Manera discloses the housing 50 has a flange portion 52 extending radially that engages the base 22 (figs 4 and 8).

10. With respect to claims 6 and 7, Manera discloses the base 22 defines a plurality of ribs, the ribs defining a step for supporting the housing. The ribs and steps are not labeled with a reference number and therefore Figures 2A (22), 8 and 9 respectively are reproduced below with arrows indicating the ribs and steps for clarity:

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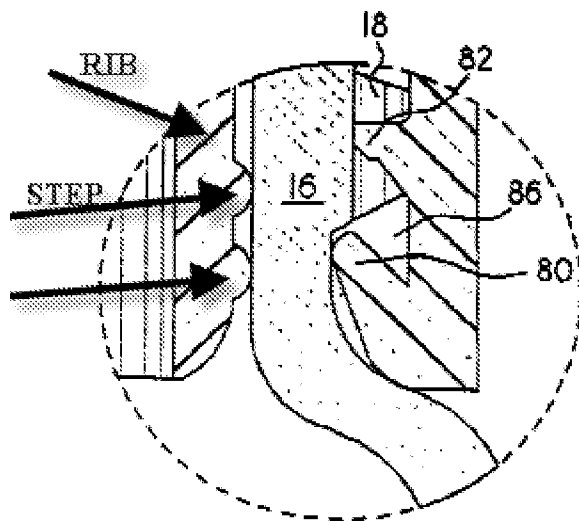
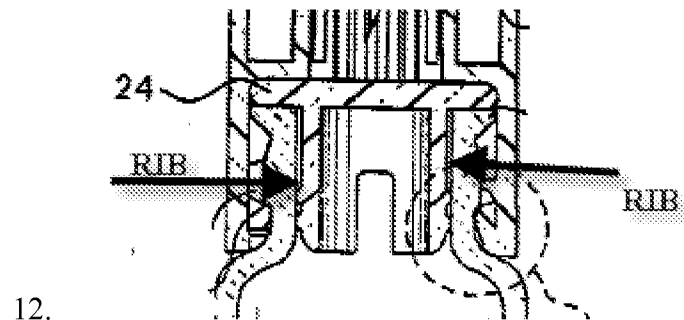
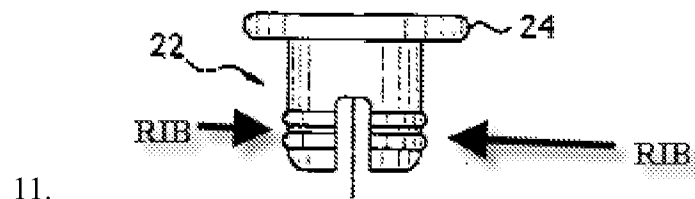


Fig. 9

13.

14. With respect to claims 10 and 11, Manera discloses a cap 53 to removably enclose an opening 51 of the housing 50 which provides a fluid seal with the housing (c. 4, ll. 4-5).

15. With respect to claims 47 and 51, Manera discloses the holder 60 includes an internal access cannula for accessing the evacuated tube 30 and directing fluid into the evacuated tube (figs. 3 and 14-16).

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16. With respect to claim 49, Manera discloses an evacuated tube 30.
17. With respect to claim 52, Manera discloses the housing 50 and holder 60 include respective connectors for releasably mounting the holder to the housing (figs. 2A and 8).

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

20. Claims 9, 12 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Manera.

21. With respect to claim 9, Manera discloses the claimed invention except for the base included a plurality of sidewall extensions being separated by cutout features. As best depicted in Figure 3, Manera teaches the holder 60 includes a plurality of sidewall extensions 66 separated by cutout portions. Manera teaches the sidewall extensions perform the function of engaging the

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holder to engage the tube within the holder. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the base of Manera comprising the sidewall extensions since either location would perform the function of engaging the components for assembly and it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

22. With respect to claim 12, Manera discloses the claimed invention except for the removable cap includes a finger grip. Manera teaches, at c. 4, ll. 14-15, that the cap 53 can be removed by a person wishing to use the apparatus, therefore providing motivation for the cap to be removed by hand. Therefore the cap of Manera is capable of being removed by hand, i.e. with the fingers. Therefore the cap of Manera is fully capable of being removed by finger grip and therefore fulfills the claimed limitation.

23. With respect to claim 44, Manera discloses the claimed invention except for the first and second connectors are male and female luer connectors. Manera teaches the connectors are capable of performing the function of sealingly coupling the components to establish fluid communication therebetween. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the connectors of Manera comprising luer connectors since luer connectors are well known in the art for sealingly coupling connecting components and as such it would have been obvious to utilize them.

Response to Arguments

24. Applicant's arguments with respect to claims 1-7, 10-11, 45, and 47-52 have been considered but are moot in view of the new ground(s) of rejection.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginger T. Chapman whose telephone number is (571)272-4934. The examiner can normally be reached on Monday through Friday 9:30 a.m. to 6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ginger T Chapman/
Examiner, Art Unit 3761
11/18/08
/Tatyana Zalukaeva/
Supervisory Patent Examiner, Art Unit 3761